IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. (1) DONALD BOOKER, Defendant.	)	No. 3:22-cr-00034- KDB

STATEMENT OF JESSICA ROLLINS, RN

Jessica Rollins, Registered Nurse (RN), will testify at the request of the Government as an expert on the urine drug testing policy of the North Carolina Medicaid Program (NC Medicaid), including the requirements of medical necessity, the meaning of certain Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes, and the submission of claims to NC Medicaid through its internet portal NCTracks.

Nurse Rollins' *Curriculum Vitae*

Ms. Rollins is currently the Registered Nurse Supervisor for Medical Health at NC Medicaid Division of Health Benefits (DHB) section of the NC Department of Health and Human Services. Her current duties as RN Supervisor for Medical Health include supervising a team of seven RNs and assisting with the creation and revision of medical clinical coverage policies for direct claims to NC Medicaid.[1] Ms. Rollins has been a RN Supervisor for Medical Health since August 2018. Prior to becoming a supervisor, from 2014 until 2018, Ms. Rollins

[1] NC Medicaid is also administered through local management entities and managed care organizations (LME-MCOs).

was a RN consultant with NC Medicaid. Her duties included consulting for cardiac, spinal, and opioid treatment, and drafting the drug testing policy.

Ms. Rollins has been a practicing RN since 2003. She received an associate degree in nursing from Vermont Technical College in Randolph, Vermont in 2003. Throughout her nursing career, Nurse Rollins has been a hospital nurse working on cardiac units, intensive care units, or step-down units. Ms. Rollins was a staff nurse performing critical care at University of Vermont Medical Center from 2003 until 2005. In 2005, Nurse Rollins began travel nursing,[2] which lead her to a position in 2006 at New Hanover Regional Medical Center in Wilmington, NC and later at Duke Regional Hospital in Durham, NC. From October 2006 through January 2012, Nurse Rollins worked in critical care at the Heart Center at WakeMed in Raleigh, NC. From 2008 through 2017, Nurse Rollins worked at the University of North Carolina's REX Hospital in Raleigh, N.C. From April 2013 through August 2014, Ms. Rollins worked as a nurse clinician and nursing supervisor for the North Carolina Department of Public Safety at Central Prison in Raleigh, NC.

Nurse Rollins' Duties at NC Medicaid

Ms. Rollins' work at DHB involves the development of policies which apply to medical services billed directly to NC Medicaid. Whenever there is a request to cover certain services or procedures, she helps to develop the clinical coverage policy for that service. That policy is then submitted to a physician advisory group made up of doctors from all specialties who review the policy and make suggestions. The physician advisory group then votes on the policy which is followed by a public comment period. After implementation, the clinical coverage policies can be found online on the NC Medicaid website and can be accessed by providers and the public.

[2] Travel nurses take temporary nursing positions in high-need areas.

NC Medicaid releases bulletins to providers regarding new policies or revisions and have meetings with stakeholders.

As part of her duties in developing Medicaid polices, Nurse Rollins is familiar with the NC Medicaid program overall, its federal funding, terms and concepts used in the medical industry, and NC Tracks—DHB's electronic portal for the enrollment of Medicaid providers and submissions of NC Medicaid claims.

NC Medicaid Overview

Nurse Rollins will explain that NC Medicaid is a joint federal and state program that gives health coverage to people with limited income and resources. Unlike Medicare—which is federal health insurance for anyone age 65 and older, and some people under 65 with certain disabilities or conditions—Medicaid has income limits. For example, in 2022, a single person would have to earn less than $18,075 to be eligible for Medicaid, a family of four persons under $36,908.[3] North Carolina is one of 12 states that have not yet expanded Medicaid under the Affordable Care Act. Nevertheless, NC Medicaid supports the health and wellbeing of more than 2.3 million North Carolinians, nearly one in four people across the state.[4] Many Medicaid beneficiaries in North Carolina are children under the age of 18. NC Medicaid receives funding from the federal government and in return must follow certain guidelines established by the United States' Department of Health and Human Services. NC Medicaid polices are designed to comply with federal requirements and provide necessary care to low income beneficiaries.

[3] https://www.dph.ncdhhs.gov/wch/families/hchcoutreach.htm

[4] https://medicaid.ncdhhs.gov/about-us.

Medicaid provides health care services to individuals who are eligible beneficiaries, it does not screen populations for public health needs.

Nurse Rollins will explain to the jury certain medical terms and acronyms used in the medical industry. First, she will explain "medical necessity." The Centers for Medicare and Medicaid Services (CMS) defines medical necessity as "health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine."[5]

Medically necessary services are covered by NC Medicaid when they are provided to, or ordered for, eligible beneficiaries by medical professionals such as physicians, psychiatrists, physician assistants, and nurse practitioners. Medical professionals are "rendering providers" when they directly perform a service and "referring" or "ordering" providers" when they order non-physician services for a beneficiary, such as a laboratory test or x-ray. A rendering or servicing provider is someone who provides medically necessary services. Rendering or servicing providers often work for a group, facility, agency, organization that has enrolled with NC Medicaid as a "billing provider." A certified clinical laboratory may be "rendering" provider of medically necessary drug tests ordered by a referring provider. If enrolled with NC Medicaid, the laboratory may also be a billing provider of drug testing services. Rendering, referring, and billing providers are recognized by NC Medicaid through their National Provider Number (NPI). An NPI is a unique identification number issued by CMS for covered health care providers.

Rendering, referring, and billing providers must enroll with NC Medicaid through its internet portal "NCTracks." NCTracks is used by DHB and other state agencies to process

[5] https://www.medicare.gov/glossary.

claims for payment. Enrolled providers submit claims for payment of covered health care services through the NCTracks' provider portal. In order to facilitate expeditious reimbursement, NC Medicaid generally pays claims submitted by providers without requesting proof of service, such as clinical notes. Providers are required to maintain documentation of their services for a certain period of time and may be required to produce them if audited. Providers that do not follow DHB policies may be placed on "prepayment review," which would require the provider to seek DHB approval before submitting a claim.

In this case, it is important to note that in North Carolina providers of behavioral health services such as psychosocial rehabilitation, substance abuse comprehensive outpatient treatment (SACOT), substance abuse intensive outpatient therapy (SAIOP), and other outpatient therapies are managed by regional LME/MCOs—not direct NC Medicaid. However, drug testing ordered by a medical professional for beneficiaries enrolled in behavioral health programs are sent directly to NC Medicaid, not the LME/MCO. The rendering providers for behavioral health services may include licensed clinical social workers (LCSWs), but psychiatrists are the only behavioral health providers also authorized to provide medical care to a beneficiary, including drug testing.[6]

In order to submit a claim on NC Tracks, the provider must provide the beneficiary's unique Medicaid number and the date of service. A beneficiary is assigned a Medicaid number after meeting with a DHB officer who determines whether the person is eligible for Medicaid benefits. A direct NC Medicaid claim must also include the NPIs for the billing, rendering, and/or referring providers.

[6] Nurse Rollins' expertise is with medical procedures and policies and not behavioral health.

NC Medicaid claims must also include appropriate diagnosis and procedure codes. A diagnosis code—also known as an ICD code—refers to the International Classification of Diseases, which is a system used to describe all known diseases and injuries. The Current Procedural Terminology (CPT®) codes are a uniform means of describing medical services and procedures used to treat a diagnosed disease or injury. Healthcare Common Procedure Coding System (HCPCS) codes are used to identify non-physician services—such as ambulances and prosthetics. Level II HCPCS codes identify products, supplies, and services not included in CPT. Level II codes consist of a letter followed by four numeric digits.

Urine Drug Testing

Ms. Rollins has been involved with developing NC Medicaid's urine drug testing policy since 2015. Urine drug testing is used to test for the presence of illicit and non-illicit drugs in a Medicaid beneficiary's urine. Urine drug testing has different levels of testing. Presumptive testing—also known as qualitative testing or a screen—is used to determine whether the presence of a category of drug(s) is found in urine specimen. Definitive testing—also known as quantitative testing or a confirmation—is more in depth and can show exactly which drug(s) are in a urine specimen and the levels of metabolite found therein. Definitive testing uses more sophisticated equipment and medical expertise than presumptive testing and is reimbursed at a higher rate than presumptive testing. For example, as of January 1, 2016, a presumptive test billed under CPT Codes 80305, 80306, 80307 were reimbursed in the amount of $72.12, whereas a definitive test billed under HCPCS Code G0483 was reimbursed in the amount of $195.86.[7]

[7] CPT and HCPCS codes are reviewed and edited periodically to be sure they are accurately descriptive of the services they represent.

In 2016, DHB published a bulletin that prohibited drug testing laboratories from billing for each drug tested—a practice known as "unbundling." Before this policy, drug testing laboratories could bill multiple CPT codes for each drug that was definitively tested. Beginning on January 1, 2016, drug testing laboratories were required to bill HCPCS codes for definitive testing of categories or panels of drugs and substances—e.g., 1 – 7, 8-14, 15-21, and 21+ drugs. Presumptive drug tests that screen for a number of drugs are billed under CPT codes 80305, 80306, 80307. The amount of reimbursement increases with the number of drugs tested in a panel.

Clinical Coverage Policy No: 1S-8, "Drug Testing for Opioid Treatment and Controlled Substance Monitoring" was published effective November 1, 2017. NC Medicaid Special Bulletins addressing urine drug testing were published beginning in February 2016. Before 2016, the CMS' National Correct Coding Initiative (NCCI) included limits on how certain drug testing CPT codes could be billed together by the same provider. Even before 2017, urine drug testing had to be ordered by a medical practitioner. This means valid drug testing claims must have been ordered by a physician, psychiatrist, physician assistant, or nurse practitioner for a medical reason.

Moreover, the referring medical professional must establish care with a patient in order to have medical necessity for a drug test. To establish care, a medical professional must meet and evaluate a beneficiary to determine what type of drug testing is needed. A medical professional then makes professional recommendations based on the individual needs of a Medicaid beneficiary and issues individual orders such as drug testing based on that need.

Drug Testing for Opioid Treatment and Substance Abuse Disorders

Clinical Policy No. 1S-8 was issued to establish a cohesive clinical coverage policy regarding urine drug testing. Effective November 1, 2017, Clinical Policy No. 1S-8 states that urine drug testing is medically necessary for the treatment of toxicity,[8] substance use disorder, and chronic pain.

Clinical Policy No. 1S-8 also clarified the requirements of medical necessity for drug testing. Before ordering a drug test, the referring provider must conduct a physical examination of the patient, review previous lab tests findings, the patient's history of drug usage, and whether drug usage in the patient's community and family present a high risk.[9] The test must be tailored to the individual patient, which can only be done with direct contact with the patient.

Definitive tests are medically necessary when ordered by a medical professional after review of a presumptive test. "Reflex testing" is when a lab performs a definitive test without a separate order to test for an unexpected presumptive result. Definitive tests to verify a presumptive positive test or to confirm the absence of a prescribed drug when the presumptive test returns a negative result are covered by NC Medicaid.

The 2017 policy also specified the frequency and number of drug tests that NC Medicaid would cover based on the following beneficiary criteria:

1. History, physical examination, and previous laboratory findings;
2. Beneficiary report of use and prescribed medications;

[8] "Toxicity" refers to a beneficiary who presents to any clinical setting with symptoms of substance use toxicity, such as coma, altered mental state, or seizures. Presumptive drug testing is used to stabilize the patient while awaiting rapid testing, then definitive testing to determine the cause(s) of the symptoms.

[9] In March 2020, NC Medicaid issued Clinical Coverage Policy No: 1H a telehealth policy which allows medical professional to use two-way real-time interactive audio and video to provide and support health care services when participants are in different physical locations.

3. Suspected misused substance(s);

4. Community usage; and

5. Substances that may present high risk for additive or synergistic interactions with prescribed medication such as benzodiazepines or alcohol.[10]

The policy requires that the beneficiary's health record contain documentation of appropriate testing frequency based on the stage of treatment or recovery, rationale for all drug class(es) ordered, results of laboratory testing, and how the results are to be used to guide care for both presumptive and definitive drug testing. The policy provided the following rules for the frequency of testing:

1. For a beneficiary with **zero (0) to thirty (30) consecutive days of abstinence**, presumptive and definitive drug testing is expected at a frequency not to exceed once per calendar week.

2. For a beneficiary with **thirty-one (31) to ninety (90) consecutive days of abstinence**, presumptive and definitive drug testing is expected at a frequency not to exceed twice per thirty (30) consecutive calendar days.

3. For a beneficiary with **greater than ninety (90) consecutive days of abstinence**, presumptive and definitive drug testing is expected at a frequency not to exceed once per thirty (30).[11]

NC Medicaid allows the use of standing orders, which are requests by a medical professional for repetitive testing of a single beneficiary to monitor a condition for a limited number of visits using a predetermined set of tests. NC Medicaid also permits the use of blanket orders, which are requests by a medical professional for repetitive testing of a class of beneficiaries without an individualized assessment of need. After November 1, 2017, standing

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[10] *See* Clinical Coverage Policy No:1S-8, *Drug Testing for Opioid Treatment and Substance Abuse Disorders,* at Section 3.2.1.2(b) Treatment of Substance Abuse Disorder, Indications for of Testing.

[11] *Id*. at Section 3.2.1.2(b) Treatment of Substance Abuse Disorder, Frequency of Testing (emphasis in the original).

and blanket orders must meet the criteria for medical necessity specified in Clinical Coverage Policy No. 1S-8. This means that rendering and referring providers using standard and blanket orders must maintain documentation for medical necessity for every patient and every drug test. Provider records can be requested and audited by NC Medicaid. Providers who do not maintain such documentation can be placed on pre-paid review.

Before November 1, 2017, it was well known in the medical and behavioral health fields that an LCSW could administer a urine test under a medical professional's standing or blanket order only if a medical professional had established care with that patient. A non-medical professional was never allowed to order a drug test under a standing or blanket order for a beneficiary that was not being treated by a medical professional.

Nurse Rollins' Review and Signature

I, Jessica Rollins, RN, have reviewed the above and approve it as my statement.

12/19/2022
Date

Jessica Rollins
Jessica Rollins, RN

From: Rollins, Jessica
To: Savage, Mike (USANCW)
Cc: [redacted]
Subject: Re: [External] Approved Rollins Expert Statement
Date: Monday, December 19, 2022 8:35:33 PM

Hi Mike,

I have received and reviewed the final draft of the expert statement. I agree with all information and the electronic signature shall stand as a facsimile of my signature.

Thank you,

Jessica Rollins

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